ANTIMICROBIAL DIVISION

RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH

EFFICACY REVIEW I

Srinivas Gowda 10/21/97

IN: 6/26/97 OUT: 10/8/97

Reviewed by Michael Nieves 10-21-97 Date 10/8/97

LAN Code

EPA Reg. No. or File Symbol 1677-RIL

EPA Petition or EUP No. None

Date Division Received 3/10/97

Type Product Acid Liquid Sanitizer for Food Contact Surfaces

MRID No(s) 442364-01, 442148-01, 02, 442316-01

Product Management Team PM 31

Product Name KX-6085

Company Name Ecolab

Submission Purpose:

The registrant is submitting efficacy data for sanitizing claims on food contact surfaces with proposed labeling.

Type Formulation Liquid

Active Ingredients(s)

Peroxyacetic acid........................ 15.2%
Hydrogen Peroxide........................ 11.2%

Rejected

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Type Product Acid Liquid Sanitizer for Food Contact Surfaces

MRID No(s) 442364-01, 442148-01, 02, 442316-01

Product Management Team PM 31

Product Name KX-6085

Company Name Ecolab

200.0 **Introduction:**

200.1 **Uses: Food Contact Sanitizer**

200.2 **Background Information:**

The registrant is submitting efficacy data for sanitizing claims on food contact surfaces with proposed labeling.

200.3 **Factors Affecting Amount/Type of Data Required:**

None

201.0 **Data Summary**

None

201.1 **Abstract of Test Reports:**

None

201.2 **Brief Description of Tests:**

1. "KX-6085 Food Contact Surface Sanitizing Efficacy At 120°F (EPA Registration No. 1677-" by Burton M. Baum of Ecolab, 840 Sibley Memorial, Mendota Heights, MN 55118, dated January 6, 1997. MRID No. 442364-01.

2. "OXY-15 Non-Food Contact Surface Sanitizing Efficacy (EPA Registration Number No. 1677-)" by Pamela Reed of Ecolab, 840 Sibley, Mendota Heights, MN 55118, dated July 28, 1995, MRID No. 442148-01.

3. "OXY-15 Non-Food Contact Surface Sanitizing Efficacy (EPA Registration Number No. 1677-)" by Pamela Reed of Ecolab, 840 Sibley, Mendota Heights, MN 55118, dated July 28, 1995, MRID No. 442148-02.

4. "OXY-15 Food Contact Supplemental Surface Sanitizing Efficacy (EPA Registration Number No. 1677-)" by Pamela Reed of Ecolab, 840 Sibley, Mendota Heights, MN 55118, dated July 28, 1995, MRID No. 442316-01.

201.3 **Data Summaries**

None

201.4 **Other Summarized Results:**

See Recommendations under 202.0.

202.0 **Accepted Data**

1. "KX-6085 Food Contact Surface Sanitizing Efficacy At 120°F (EPA Registration No. 1677-" by Burton M. Baum of Ecolab, 840 Sibley Memorial, Mendota Heights, MN 55118, dated January 6, 1997. MRID No. 442364-01.

The submitted efficacy data developed by the AOAC Germicidal and Detergent Test Method and the AOAC Phenol Coefficient Test Method appear adequate to support effectiveness of the product as a sanitzing rinse for previously cleaned hard, non-porous, food contact surfaces against Staphylococcus aureus and Escherichia coli when diluted 1 oz/30 gallon in the presence of 510 ppm AOAC hard water after a contact time of 30 seconds at 119.5 - 120.3°F.

2. "OXY-15 Non-Food Contact Surface Sanitizing Efficacy (EPA Registration Number No. 1677-)" by Pamela Reed of Ecolab, 840 Sibley, Mendota Heights, MN 55118, dated July 28, 1995, MRID No. 442148-01.

The submitted efficacy data developed by the EPA Sanitizer Test Method for inanimate, nonfood contact surfaces and the AOAC phenol Coefficient Test Method appears adequate to support effectiveness of the product as a non-food contact surface sanitizer on hard, nonporous surfaces against Staphylococcus aureus and Enterobacter aerogenes when diluted to 30 ppm peroxyacetic acid in the presence of 500 ppm AOAC hard water after a 5 minute contact time at 21°C.

3. "OXY-15 Non-Food Contact Surface Sanitizing Efficacy (EPA Registration Number No. 1677-)" by Pamela Reed of Ecolab, 840 Sibley, Mendota Heights, MN 55118, dated July 28, 1995, MRID No. 442148-02.

The submitted efficacy data developed by the EPA Sanitizer Test Method for inanimate, nonfood contact surfaces and AOAC Phenol Coefficient Test Method appears adequate to support effectiveness of the product as a non-food contact surface sanitizer on hard, nonporous surfaces against Listeria monocytogenes, Salmonella typhimurium, Pseudomonas aeruginosa, Escherichia coli, Pediococcus damnosus ATCC 25248, Lactobacillus buchneri 11305 when diluted to 30 ppm peroxyacetic acid in the presence of 500 ppm AOAC hard water after a 5 minute contact time at 21°C.

202.1 **Rejected Data**

4. "OXY-15 Food Contact Supplemental Surface Sanitizing Efficacy (EPA Registration Number No. 1677-)" by Pamela Reed of Ecolab, 840 Sibley, Mendota Heights, MN 55118, dated July 28, 1995, MRID No. 442316-01.

This data package was rejected because the dtaa was developed for a contact time of two minutes. The data must be developed for a contact time of 30 seconds. Please refer to attached copy of DIS/TSS-04: Sanitzing Rinses (for previously cleaned food contact surfaces)

203.0 **LABELING**

The proposed labeling is **UNACCEPTABLE:**

The registrant has submitted four data packages (MRIDs: 442364-01, 442316-01, 442148-01 and 442148-02). Except for the first package 442364-01, the rest of the data packages express the effective use-dilution in terms of ppm of peroxyacetic acid (either 150 ppm for MRID No. 442316-01 or 30 ppm for MRID No. 442148-01 and 442148-02). The registrant must submit to EPA a label that clearly delineates how to prepare such solutions.

ALSO:

The registrant claims that the product 1677-RIL is substantially similar to two other Ecolab products, Oxy-15, EPA Reg. No. 1677-164 and Oxonia Active, EPA Reg. No. 1677-129. The registrant wants to use the claims appearing on EPA Reg. 1677-129.

The label for EPA Reg. 1677-129 show that although both products have the same active ingredients, they are not substantially similar. The registrant may use the claims on EPA Reg. No. 1677-164, since this product is substantially similar to EPA Reg. No. 1677-RIL.

PRODUCT	HYDROGEN PEROXIDE	PEROXYACETIC ACID	INERTS
*1677-RIL	11.2%	15.2%	73.6%
*1677-164	11.0%	15.0%	74.0%
1677-129	27.5%	5.8%	66.7%

Notice that in 1677-129, Hydrogen Peroxide is the main Active Ingredient and in 1677-RIL and 1677-164 it is the Peroxyacetic acid.

due to rejected MRID 442316-01

Also, the registrant must remove any food contact surface sanitizing claims against Listeria

monocytogenes, Salmonella typhimurium, Pseudomonas aeruginosa, Saccharomyces cerevisiae, Vibrio cholerae, Pediococcus damnosus and Lactobacillus bucneri.

Finally, under "Sanitizing Tableware": the registrant must specify a 1 minute contact time.

DIS/TSS-4 Jan. 30, 1979

EFFICACY DATA REQUIREMENTS

Sanitizing rinses (for previously cleaned food-contact surfaces).

Sanitizers applied to food contact surfaces are defined as incidental food additives under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 201 et seq.), and require establishment of a food additive tolerance. Recommendation of a potable water rinse after treatment does not preclude this requirement.

(1) Halide chemical products. Efficacy of sanitizing rinses formulated with iodophors, mixed halides, and chlorine bearing chemicals must be substantiated with data derived from the AOAC Available Chlorine Germicidal Equivalent Concentration Method.

(i) Test requirements. Data from one test on each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against S. typhi are required.

(ii) Performance standard. Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine. (The reference standard is sodium hypochlorite.)

(2) Other chemical products. Efficacy of sanitizing rinses formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations must be substantiated with data derived from the AOAC Germicidal and Detergent Sanitizers Method.

(i) Test requirements. Data from the test on one sample from each of 3 different batches, one of which is at least 60 days old, against both E. coli and S. aureus are required. When claims for the effectiveness of the product in hard water are made, all required data must be developed at the hard water tolerance claimed.

(ii) Performance standard. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and percentage reduction over the control. The minimum concentration of the product which provides the results required above is the minimum effective concentration.